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The price **you** pay **for the** drug **not** taken.
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ABSTRACT: Patient noncompliance with drugs prescribed by doctors and hospitals is alarmingly high as it is reported that around 50% of prescriptions are not taken. Around 10% of hospital admissions are caused by noncompliance. The chief cause for this attitude is stinting on drug costs and plain ignorance about the effect of prescribed drugs. One solution to this problem may come in the form of improved packaging of medicines and the easy availability of compliance monitoring equipment which reminds the patient about such details as medication time and amount to be taken.

TEXT:

Poor compliance sabotages even the best therapies. Here's a look at what it could be costing you.

How big is the problem of patient noncompliance to pharmaceutical therapies? According to Daniel Gerner, chairman of the Healthcare Compliance Packaging Council in Washington, D.C., it's enormous. "Of the 2 billion+ prescriptions filled each year, approximately half are taken improperly," he says. "We're spending between $60 and $100 billion a year to treat problems caused by noncompliance." It's the direct cause of 10 percent of all hospital admissions. Noncompliance to regimens for heart disease alone results in 125,000 avoidable deaths every year, Gerner says.

According to University of Arizona Dean of the School of Pharmacy Lyle Bootman, the actual costs are probably even higher. "Understand, though, that compliance - or rather the lack of it - is only one of the factors." In hospital and long-term care settings the drivers of drug mortality and morbidity are more likely to be overmedication, drug interactions and improper dosing, he says. "But on the ambulatory side, the problem is noncompliance to therapy."

In terms of outcomes, the consequences of noncompliance are equally troublesome. "Patients don't recover," says Ray Bullman, executive director of the National Council on Patient Information and Education. "Conditions worsen. And what looks like a poor therapy is actually a case of poor compliance." The medication may then be abandoned or the dosage increased - which increases the chance of side effects. It may also mean more tests. But what was actually needed was not something else or more of what the patient had been getting. All that was missing was patient adherence to the original protocol.

Maintenance therapies for asymptomatic conditions are especially prone to noncompliance. According to Gerner, rates of compliance are about 53 percent among hypertensive patients, 46 percent for asthmatics and 33 percent for patients on antibiotic therapies.

Earl S. Ward, associate dean and professor at Mercer University Southern School of Pharmacy in Atlanta, makes a strong case for improved compliance: Medical expenses for hypertension are running at about $25 billion per year, says Ward. "NIH data show that between 1972 and 1994, improved therapies for hypertension cut deaths from stroke by 59 percent and deaths from heart disease by 53 percent. We also know that if we start therapy early and the patient remains compliant, we can avoid or reduce the incidence of those bad outcomes," Ward says. Unfortunately, just over half of hypertensives are on any kind of therapy at all.

There are two ways to look at that, Ward continues. "We could congratulate ourselves for treating the 53 percent, while noting that if you brought in the other 47 percent, treatment costs for hypertension would just about double." On the other hand, the long-term picture for many in that untreated cohort will include stroke, heart disease, serious disability, coronary artery disease, renal failure and premature death. The costs of treating those complications will be enormous. "Wouldn't it make financial sense to avoid some of those costs by getting those outliers into treatment earlier? It certainly makes sense from the point of view of patient care," he says.

Solutions, anyone?

Determining the best way to address noncompliance is no easy task. Says Bullman, "Some blame it on the patient; others put most of the onus on health care professionals."

Steven Hass, a health economist and past chair of the Task Force for Compliance, identifies information "disconnects" as the main stumbling block. "Sometimes it's patients," Hass says. "They do their own cost/benefit analyses and decide not to have the prescription filled. When we asked patients why nearly 20 percent of prescriptions go unfilled each year, we found that in 57 percent of the cases, the patient simply decided to do without the medicine. Nineteen percent 'didn't want to' fill it, and about 15 percent decided the drug cost too much."

Even among the 80 percent of patients who conscientiously fill their prescriptions, compliance is uncertain. Only if a patient ends up back in the examining room complaining of the same symptoms can the physician even begin to suspect noncompliance. Payers don't know either, says Hass, and probably wouldn't know how to address it cost effectively if they did.

But improving compliance can reduce costs. Hass cites a year-long study of 258 Medicaid patients, all insulin-dependent diabetics. They were randomly assigned to one of four groups: standard care (verbal counseling by a pharmacist at time of refill); standard care plus written reminders (postcards and mailers indicating drug regimen requirements); standard care plus unit-of-use packaging; and standard care plus reminders and unit-of-use packaging.

"For both the reminder and the unit-of-use groups," says Hass, "Rx costs were up, indicating better compliance. But costs of office visits, lab work and hospitalization were all lower than for the standard care group. Indeed, for the group receiving both reminders and unit-of-use packaging, office visit costs were down by an average of $67, lab costs were down $18, and hospital costs by an average of $108. Total savings per patient for those in the last group were about $68, after the higher prescription costs were factored in."

A University of Southern California study demonstrates the high costs of failure to comply. It found that nearly 86 percent of new antihypertensive drug therapy patients interrupted or stopped purchasing any form of antihypertensive during the first year. Patients who interrupted therapy used an additional $873 each for health care in that time frame, minus a reduction in Rx cost of $281. The higher costs were primarily due to increased hospital expenditures.

Evanston (Ill.) Hospital's Congestive Heart Failure Program tries to keep newly released outpatients from rapid readmission. Prior to the program's start-up, about 25 percent of CHF patients were admitted, discharged and readmitted days or weeks later.

Randall E. Williams, the physician who directs the program, designed an outpatient compliance program centered around an automated telemedical management system, which permits daily patient reporting - and clinician evaluating - of weight changes and other symptoms. "Patients are flagged and slated for intervention," says Williams. The intervention may be in the form of a call or an appointment to help the patient better manage the condition.

Since implementation, Evanston's average length of stay for CHF

patients has dropped from 6.2 to four days. Its readmission rate has fallen remarkably - from 19 to less than 3 percent. Williams estimates the program has reduced direct treatment costs by 60 percent and saved about $1.6 million.

Indubitably, improving compliance can improve patient care and, at least in some cases, it seems to save money. In an era of 20 percent per year increases in the managed care "pharmacy spend," however, the difference between seeming and being can be millions of dollars.

"Compliance is this huge shadow," says Otto Wolke, vice president, pharmacy services, Geisinger/Penn State Health Plan (Danville, Pa.). "A couple of years ago we looked at compliance with anticonvulsives. We measured medication possession rates - who was filling and refilling, and who wasn't. We found that patients whose possession rates were 70 percent had fewer ER visits than patients in the 50 and 60 percent range."

At the same time, improving compliance drives up costs. "It's simple arithmetic," says Wolke: "Better compliance equals more utilization, more utilization equals higher costs. That's a fact." What's often only conjectural is whether there will be a big payback in reduced office and ER visits and hospitalizations.

Wolke worries about the effect of compliance on inadequate or inappropriate regimens. A plan may invest in a compliance system that works very well at keeping patients on drugs which, though costly, have no particular value for those patients. "That's the great fear with some of the new biotech remedies," he says. "They're very costly, but will they make that much of a difference for all the patients who take them?"

Plan sponsors have much the same misgivings. "The connection between better compliance, increased utilization and higher costs has not been lost on employers," says Bootman. "I've had CEOs say that very thing to me. And I say, 'Yes, that's true. If you increase compliance you will increase utilization. '"

That, he contends, is the real concern: If you increase utilization, you spend more. However, there is a big "on the other hand" to that argument: payback down the road. "But you do need to assess that with outcomes research," Bootman concludes.

Patterns of noncompliance

A report by the National Council of Patient Information and Education cites six types of behavior often associated with poor compliance:

Poor patient/provider communication. Providers may fail to address compliance directly, such as explaining the importance of taking all the medicine, asking about patients' intentions and discussing concerns or barriers to compliance.

Unresolved patient concerns. These may include perceptions about the seriousness of the illness or disagreement with the diagnosis or treatment.

Provider issues. These include the provider's assumption that compliance is the patient's responsibility and the provider's poor communication skills and inadequate knowledge of behavior change strategies.

Special patient-population issues. Providers may not be adequately informed about factors that can inhibit compliance in some patient populations.

Regimen-related barriers. A therapy's side effects can cause noncompliance, as can lifestyles that conflict with a regimen's requirements.

Environmental barriers. Social isolation also can affect compliance, as can such factors as lack of transportation to the pharmacy.

"We've found that the single-intervention compliance strategy is rarely effective, especially with regard to compliance to therapy for chronic conditions," says Bullman. Some studies indicate that patients with prolonged health problems often show lapses in compliance, especially where the treatment is preventive, the condition is mild or asymptomatic and the consequences of noncompliance are delayed. Interventions combining

educational and behavioral support have greater success.

Addressing poor compliance

Eagle Managed Care, a pharmacy benefit manager in Camp Hill, Pa., and managed care giant Kaiser Permanente in San Francisco, have developed multi-intervention programs that target noncompliance. Eagle's is built around a telecommunications center called Compli-Line that features out-call and call-in workstations.

One out-call application is the refill reminder. Any patient whose refill is overdue receives a phone call from a Compli-Line staffer. If there is no answer, a postcard is mailed reminding the patient that it's time to refill the prescription.

"When patients answer," says an Eagle spokesman, "Compli-Line personnel politely inquire whether they may speak to them about their medication. If they say No, we thank them for their time and hang up. When patients give permission for the call to continue, we remind them about the overdue refill and give them an opportunity to speak to a pharmacist about their therapy - right then and there. We also inform them we can have the refill processed and ready to be picked up."

Sixty to 70 percent of the time, the patient takes advantage of that service and gets the refill, the PBM reports. When the patient refuses, Eagle tries to find out why. Often, it's because there is still a lot of medication left from the previous refill - a sign of poor compliance. Pharmacists are encouraged to contact physicians, especially in cases where noncompliance could have serious consequences.

"If you can keep chronically ill patients compliant, you not only improve their health status and quality of life and save dollars, but in some instances you can even save lives," the spokesman says.

Kaiser and the University of Southern California conducted a three-year, 6,000-patient study measuring the efficacy of two models of pharmacist-patient counseling. The first, mandated by California law, requires pharmacists to explain newly prescribed medications to patients, including how to take the drag, why it's important to comply and what side effects might occur. The second adds in-depth and ongoing consultation and monitoring.

While both reduced hospitalizations resulting from noncompliance or drug interactions, preliminary analyses indicate that patients receiving more education and monitoring are more likely to use medications correctly. "Patients in the more intensively monitored group were targeted because they were deemed more at risk," says the principal investigator. "Their histories showed frequent ER visits or a more serious disease state, perhaps with comorbidities. These are the patients you want to work with to keep compliant, both to improve outcomes and keep down costs."

Compliance technologies

Something as simple as a change in packaging can also improve compliance. "A study of estrogen replacement therapy compliance found that patients receiving their medication in traditional bottles had only a 30 percent compliance rate," reports HCPC's Gerner. "But compliance jumped to 82 percent for patients who were switched to a unit-dose blister-card package."

Sophisticated technology is the common element of a new generation of compliance aids. Jean-Michel Metry, European managing director at Aprex Corp., Zug, Switzerland, describes an electronic monitoring device called the SmartCap. It has two visual displays, one to indicate how many times the package has been opened during the present 24-hour period, the other to indicate how long it has been since the patient's last entry into the package. Errors can be further minimized by using an optional alarm that goes off at the time of each scheduled close.

Another electronic tool is the Medi-Monitor from InforMedix in Rockville, Md. Capable of monitoring 10 different medications, it includes a signal warning when it's time to take a medication, a graphics screen with preprogrammed information about the medication and interactive prompts

asking the patient about drug side effects or interactions. A built-in modem enables the patient to send the data to InforMedix, where it is analyzed and reported to the patient's physician, pharmacist or health plan.

Patients who need to monitor their glucose may benefit from another sophisticated monitoring tool. Bill G. Felkey, associate professor of pharmacy care systems at Auburn University in Alabama, explains: "Several suppliers have developed finger-stick glucose monitors with memory chip enhancements. Every time the patient performs the test, the chip registers the date and the hour. This information can be easily downloaded to the pharmacist's computer.

"It's an amazing compliance tool," Felkey continues. "If you think someone will find out, you're motivated to take the medication as prescribed."

Soon to be available is "JERRY the Pharmacist," a hand-held, interactive electronic device that uses verbal cues to prompt patients to take their medicines according to regimen. JERRY also counsels patients about drug interactions and reminds them when it's time to refill.

A more conventional patient reminder System, Direct To Patient Communications, is operated by Elensys Inc., a Massachusetts-based company. Elensys uses data downloaded from client pharmacies to identify noncompliant patients, who are then sent reminder letters and packets of educational materials. However, the involvement of third-parties in the possession and processing of potentially sensitive medical information has been in the forefront of the issue of patient confidentiality. Do compliance programs fatally compromise such confidentiality?

Last spring, Elensys found itself in the center of a contretemps when some patients of CVS and Giant Food pharmacies expressed surprise and dismay at receiving medically intimate communications from a third party. Protests by patients and consumer groups, whose anger was also fueled by mailings promoting alternative treatments, prompted CVS and Giant Foods to cancel compliance monitoring and intervention contracts with Elensys.

"There's no question that patient confidentiality is a real issue," notes Cristie Cohn, vice president, clinical products development at PCS Health Systems in Scottsdale, Ariz. "You must take all precautions to ensure confidentiality - that's a given. But the issue itself is one that can be made too provocative. I've found that once the patient realizes that at the other end of the phone line a clinician is doing the intervention - that in effect the patient has his or her own personal nurse - once that happens patients start doing inbound calls. Patients now say things like, 'Thanks for caring about X, now help me with Y!'"

Enhancing the patient's role

Such interventions could improve outcomes - if patients, especially the chronically ill, can be persuaded to become more actively involved in managing their care and complying with treatment.

Diabetes is a frequent target for patient self-management. Many patients require daily doses of insulin or other medications. Needlesticks and glucose-testing devices must also be used, and patients have to be trained and encouraged to use them properly. Failure to take the medication or frequently monitor bodily changes can have devastating effects.

"To daily manage this 'complex condition, diabetic patients need a support structure," says Anita Austin, coordinator of the Diabetes Edu-Center, New Kensington, Pa. Patients need to learn about their illness and its ramifications. They need structured encouragement to stay compliant with therapy. They especially need help with diet and exercise, she says.

Austin's program starts with a one-on-one session in which she assesses the patient's condition and level of awareness about the disease, then provides basic self-management education, such as how to use the glucometer. Initial counseling is followed by a shorter session in which Austin assesses how well the patient has absorbed the information and can perform self-management techniques. There are a number of scheduled

follow-ups and, if needed, more sessions are scheduled for an additional charge. The cost to the patient is about $300 a year.

"Another important, benefit is that the patients have somewhere to go and someone to call if they have a problem or need advice - which can help avoid a medical emergency," says Austin.

Compliance, it's evident, is everyone's responsibility: the patient's, certainly, but also physicians' and pharmacists'. Health plans - and purchasers - that fail to focus on furthering compliance risk incurring large and unnecessary expenditures.

Some also consider compliance an obligation - and perhaps an opportunity - for the drug maker. As Steven Hass points out, "If the typical pharmaceutical manufacturer has sales of $6 billion and if 75 percent of those sales are retail and if - as the Task Force for Compliance determined - 20 percent of all prescriptions are never filled - then that's $900 million in lost sales per year.

"Therapy management includes patient wellness, health risk assessment, therapeutic interventions and patient counseling," adds Mario Sylvestri, director of professional education, disease management and medical informatics at Hoechst Marion Roussel. "And the next piece is therapy compliance monitoring. We all need to focus more on that, developing tools and programs to help physicians and pharmacists help their patients stay on track. That way everybody wins."

SPECIAL FEATURES: illustration; graph
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